PERFORMANCE QUALIFICATION REPORT FOR AMPOULE VERTICAL ULTRASONIC WASHING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Ampoule Washing & Sterilizing Room**
DATE OF QUALIFICATION	

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AMPOULE VERTICAL ULTRASONIC WASHING MACHINE	PROTOCOL No.:

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AMPOULE VERTICAL ULTRASONIC WASHING MACHINE	PROTOCOL No.:

1.0 REPORT PRE-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The scope of this report is limited for Qualification of Ampoule Vertical Ultrasonic Washing Machine installed in Ampoule Washing & Sterilizing Room.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Approval and Compilation of the Performance Re-Qualification Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Re-Qualification Activity. • Monitoring of Performance Re-Qualification.
Production	• Review & Approval of Report. • To co-ordinate and support Performance Re-Qualification Activity.
Quality Control	• Analytical Support (Microbiological Testing/Analysis)
Engineering	• Reviewing of Re-qualification protocol for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule. • Post Approval of Performance Re-Qualification Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vertical Ultrasonic Ampoule Washing Machine
Equipment	
Manufacturer's Name	Truking Technologies Ltd.
Model	
Supplier's Name	Truking Technologies Ltd.
Location of Installation	Ampoule Washing & Sterilization Room

6.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance Qualification report.

- SOP for Operation & Cleaning of Ampoule Vertical Ultrasonic Washing Machine.
- SOP for Preventive Maintenance Ampoule Vertical Ultrasonic Washing Machine.

7.0 TESTS AND CHECKS:

7.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	**Executed and approved Design Qualification document**				
2.	**Executed and approved Installation Qualification document**				
3.	**Executed and approved Operational Qualification document**				
4.	**PQ Protocol approved**				
5.	**SOP for Operation & Cleaning of Ampoule Vertical Ultrasonic Washing Machine**				
6.	**SOP for Preventive Maintenance of Ampoule Vertical Ultrasonic Washing Machine**				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.2 Physical Parameter Test Results

Date of Test	Ampoule Size	Machine Speed

Pressure	Limit	Observation
Compressed Air Pressure	0.2 to 0.6 Mpa	
Purified Water Pressure	0.2 to 0.65 Mpa	
Circulated Water Pressure	0.2 to 0.5 Mpa	
WFI Pressure	0.2 to 0.5 Mpa	

A. Production Capacity

Cycles	Testing Time	Production Quantity	Capacity Output (pcs/min = Total no of each runs washing ampoules / actual running time
1			
2			
3			
Average production Capacity			

Acceptance Criteria:
Production Capacity - 500 pcs/ min for 1,2,3 ml & 420 pcs/ min for 5ml:(100%Speed).
Production Capacity - 400 pcs/ min for 1,2,3 ml & 336 pcs/ min for 5ml (80% Speed)
Production Capacity - 250 pcs/ min for 1,2,3 ml & 210 pcs/ min for 5ml (50% Speed)

B. Damage Rate

Cycles	Feeding Ampoules Quantity	Nos. of Broken Ampoules	Damage Rate = Total damaged ampoules x 100 / Total feeding Ampoules
1			
2			
3			
Average Damage Rate			
Acceptance Criteria: Damage rate of Ampoules should not be more than 0.5 %.			

C. Clarity Test

Cycles	Nos. of Inspected Ampoules Quantity	Nos. of Passed Ampoules	= Total no, of passed ampoules x 100 / Total Inspected Ampoules
1			
2			
3			
Average Passing rate			
Acceptance Criteria: Clarity of Ampoules should be more than 98 %.			

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.3 Riboflavin Test

Cycles	I Cycle	II Cycle	III Cycle
Date of Test			
Ampoule Size			
Machine Speed			

Ampoule no.	Observation			Verified by Quality Assurance (Sign/Date)
	I Cycle	II Cycle	III Cycle	
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AMPOULE VERTICAL ULTRASONIC WASHING MACHINE	PROTOCOL No.:

Ampoule no.	Observation			Verified by Quality Assurance (Sign/Date)
	I Cycle	II Cycle	III Cycle	
12				
13				
14				
15				
16				
17				
18				
19				
20				

Acceptance criteria: All individual washed Ampoules should be free from surface coating of riboflavin.

Note: OK – With in acceptance criteria, **Not OK** – Not with in acceptance criteria

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.4 Chloride Test

Cycles	I Cycle	II Cycle	III Cycle
Date of Test			
Ampoule Size			
Machine Speed			

Ampoule no.	Observation			Verified by Quality Assurance (Sign/Date)
	I Cycle	II Cycle	III Cycle	
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AMPOULE VERTICAL ULTRASONIC WASHING MACHINE	PROTOCOL No.:

Ampoule no.	Observation			Verified by Quality Assurance (Sign/Date)
	I Cycle	II Cycle	III Cycle	
16				
17				
18				
19				
20				

Acceptance criteria: All individual washed Ampoules should not show turbidity or opalescence after adding reagents.

Note: OK – With in acceptance criteria, **Not OK** – Not with in acceptance criteria

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.5 Glass Particle Test

Cycles	I Cycle	II Cycle	III Cycle
Date of Test			
Ampoule Size			
Machine Speed			

Ampoule no.	Observation			Checked By (Production) (Sign/Date)
	I Cycle	II Cycle	III Cycle	
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AMPOULE VERTICAL ULTRASONIC WASHING MACHINE	PROTOCOL No.:

Ampoule no.	Observation			Checked By (Production) (Sign/Date)
	I Cycle	II Cycle	III Cycle	
17				
18				
19				
20				
Acceptance criteria: The ampoule should be free from the glass particles (Visual inspection).				

Note: OK – With in acceptance criteria, **Not OK** – Not with in acceptance criteria

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.6 Endotoxin Test

Cycles	I Cycle	II Cycle	III Cycle
Date of Test			
Ampoule Size			
Machine Speed			
Sample Quantity			

S.No.	Observation			Verified by Quality Assurance (Sign/Date)
	I Cycle	II Cycle	III Cycle	
1				
Acceptance criteria: NMT 0.25 EU/ ml				

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.7 Bioburden Test

Cycles	I Cycle	II Cycle	III Cycle
Date of Test			
Ampoule Size			
Machine Speed			
Sample Quantity			

S.No.	Observation			Verified by Quality Assurance (Sign/Date)
	I Cycle	II Cycle	III Cycle	
1				
Acceptance criteria: NMT 10 CFU/100 ml				

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remarks
Verification of Documents		
Verification of Machine Performance		
Verification for Riboflavin Test		
Verification for Chloride Content Test		
Verification of glass particle Test		
Verification of Endotoxin Test		
Verification of Bioburden Test		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 DOCUMENTS TO BE ATTACHED:

- Executed Raw Data.
- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

Asst.	:	Assistant
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
EU	:	European Union
FDA	:	Food and Drug Administration
IQ	:	Installation Qualification
Kg	:	Kilogram
Ltd.	:	Limited
mm	:	Millimetre
No.	:	Number
OQ	:	Operational Qualification
PQ	:	Performance Qualification
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization
WFI	:	Water for injection

17.0 REPORT POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			